

REMARKS

Claims 1-12, 50-58, and 60-65 were pending in this application. Claims 8, 50, 54, 57, 64, and 65 have been amended and claims 3, 5, 7, 52, 56, 59, and 60 have been canceled as being drawn to a non-elected invention. New claims 66-86 have been added. Accordingly, upon entry of this amendment, claims 1, 2, 4, 6, 8-12, 50, 51, 53-55, 57, 58, and 61-86 will be pending.

Support for the amendments to the claims and the new claims may be found throughout the specification and claims, as originally filed. No new matter has been added.

Cancellation of and/or amendments to the claims should in no way be construed as acquiescence to any of the Examiner's rejections and were done solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the instant or in another patent application(s).

No additional search is required and no new issues have been raised by the amendments made herein; support for the amendments made can be found in the specification as filed and/or in the claims as previously pending. Furthermore, in view of the amendments and arguments set forth herein, the number of issues for appeal have been reduced. It is believed that the Examiner's rejections under §112, first paragraph and §112, second paragraph have been obviated by claim amendments and cancellations. Therefore, the claim amendments and cancellations made herein are permissible under 37 C.F.R. §1.116 as reducing the number of issues for appeal, and Applicants respectfully request that the present Amendment be entered.

Election/Restriction

Group I (claims 1, 2, 4, 6, and 8-12), directed to isolated nucleic acid molecules encoding human T-bet proteins, vectors, host cells and, methods of producing the protein were elected by Applicants with traverse in the Response to the the redrafted Restriction Requirement set forth in the previous Office Action. Although Applicants maintain that the Restriction Requirement is improper, claims 3, 5, 7, 52, and 56 have been canceled as being directed to a non-elected invention.

Sequence Disclosure

The Examiner states that the substitute CRF filed July 22, 2005 with Applicants' response fails to comply with the requirements of 37 C.F.R. §1.821 through C.F.R. §1.825, because the <220> Features and associated headings are missing from SEQ ID NOs:5-9.

Applicants submit herewith a substitute sequence listing to add the appropriate <220> Features and associated headings to SEQ ID NOs:5-9. Accordingly, Applicants request reconsideration and withdrawal of the rejection under C.F.R. §1.821- C.F.R. §1.825.

Priority

Applicants acknowledge the Examiners indication that U.S. Provisional Application No. 60/137,085 provides support under 35 U.S.C. § 112 for the subject matter claimed in the instant specification, including claim 50.

Withdrawal of Certain Objections/Rejections

Applicants gratefully acknowledge the Examiner's indication that the following objections/rejections have been withdrawn:

the objection to the title of the instant application;

the objection to the specification for containing embedded hyperlinks;

the objection to claim 6 for being in improper dependent format;

the objection to claims 1, 51, 55, 58, and 59 for not using the proper format for sequence identifiers;

the rejection of claims 4, 6, 8-12, 51, 53, and 54 under 35 U.S.C. §112, first paragraph, as being indefinite for the recitation of the term "a T-box binding element in DNA";

the rejection of claim 50 for the recitation of "activity selected from the group consisting of IFN- γ production, Th1-associated cytokine production, and Th1 cell differentiation";

the rejection of claim 50 under 35 U.S.C. §112, first paragraph, as being indefinite in the recitation of "Th1 cell differentiation";

the rejection of claims 4, 6, 8-12, 50, and 54 under 35 U.S.C. §112, first paragraph as not providing adequate written description for the term “at least 95% identity” as it applies to nucleic acid sequences;

the rejection of claim 53 under 35 U.S.C. §112, first paragraph, as not providing adequate written description for the term “at least 95% identity” as it applies to the amino acid sequences;

the rejection of claim 50 under 35 U.S.C. §112, first paragraph as being broader in scope than originally presented for the recitation of “Th1 cell differentiation”;

the rejection of claim 59 under 35 U.S.C. §112, first paragraph as containing insufficient direction to a fragment comprising specifically nucleotides 1-900 of SEQ ID NO:1.;

the rejection of claim 50 under 35 U.S.C. §112, first paragraph as not providing enablement for a broad recitation of a peptide that has the activity of inducing IFN- γ production;

the rejection of claims 55 and 57 under 35 U.S.C. §112, first paragraph, as not being enabling for an isolated nucleic acid comprising a fragment of at least 700 contiguous nucleotides of the nucleotide sequence of SEQ ID NO:1 or complement thereof.;

the rejection of claims 1, 2, 4, 6, 51, 53, 55, 58, and 59 under 35 U.S.C. §102(a) as being anticipated by Yang (of record, GenBank Accession No. AF093098); and

the rejection of claims 8-12 under 35 U.S.C. §103(a) as being unpatentable over Kishimoto, *et al.* (US Pat. No. 5,844,082; see entire document) in view of Yang (of record).

Rejection of Claims 50, 60, and 64 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 50 and 64 under 35 U.S.C. §112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular the Examiner is of the opinion that the recitation of the term “initiation of Th1 cell differentiation of Thp cells and Th2 cells” is indefinite. The Examiner states that “it is unclear whether the intended meaning is differentiation of Th1 cells into Thp and Th2 cells or differentiation of Thp and Th2 cell into Th1 cells.”

Without acquiescing to the validity of the Examiner's rejection and solely in the interest of expediting examination, Applicants have amended claim 50 to recite "differentiation of Thp cells and Th2 cells into Th1 cells". Accordingly, Applicants respectfully request reconsideration and withdrawal of this § 112, second paragraph rejection of claim 50 and dependent claim 64.

The Examiner has rejected claim 60 under 35 U.S.C. §112, first paragraph, as being indefinite for the recitation of "prosthetic group". In particular, the Examiner is of the opinion that claim 60 is indefinite as lacking antecedent basis in claim 57. The Examiner further states that "[a]ccording to Webster's New World Dictionary (Third College Edition, 1988, page 1080), 'prosthetic' means, as applied to chemical groups, 'designating or of any of a number of nonprotein compounds when combined chemically with a protein molecule'. Since claim 60 recites 'the nucleic acid molecule of claim 57', rather than a protein molecule, the recitation of 'prosthetic group' lacks antecedent basis".

Without acquiescing to the validity of the Examiner's rejection and solely in the interest of expediting examination, Applicants have amended claim 60 to delete the recitation of "prosthetic group". Accordingly, Applicants request reconsideration and withdrawal of this §112, second paragraph rejection of claim 60.

The Examiner has also rejected claim 64 as being indefinite and lacking antecedent basis in claim 50 for the recitation of "wherein the Th1-associated cytokine is...IL-2". In particular, the Examiner is of the opinion that "[c]laim 50 recites induction of Th1-associated cytokine production under the influence of T-bet polypeptide, while the instant specification discloses at page 14, lines 33-34, that T-bet leads to repression of IL-2 production. Therefore, recitation of IL-2 in claim 64 is inconsistent with the recitation of claim 50, and as such lacks antecedent basis".

Without acquiescing to the validity of the Examiner's rejection and solely in the interest of expediting examination, Applicants have amended claim 64 to delete the recitation of "IL-2". Accordingly, Applicants respectfully request reconsideration and withdrawal of this § 112, second paragraph rejection of claim 64.

Rejection of Claims Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claim 60 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Specifically, the Examiner is of the opinion that the “specification at page 34, lines 34-36 discloses anti-T-bet antibody labeled with a detectable substance, such as an enzyme, prosthetic group, fluorescent material, luminescent material, or a radioactive material.” The specification does not appear to disclose a nucleic acid molecule labeled with such a detectable substance, and as such, does not provide an adequate written description of the claimed limitations.

Without acquiescing to the validity of the Examiner’s rejection and solely in the interest of expediting examination, Applicants have canceled claim 60 rendering the Examiner’s rejection moot.

Rejection of Claims, Double Patenting

Applicants acknowledge the Examiner’s indication that the provisional rejection of claims 1, 2, 4, 6, 8-12, 50, 51, 53-55, and 57-59 under the judicially created doctrine of obviousness-type double patenting is maintained.

Applicants respectfully submit that upon an indication of allowable subject matter in this or the related applications Applicants will consider filing a terminal disclaimer, if appropriate.

SUMMARY

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

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Respectfully submitted,

By 

Maria Laccotripe Zacharakis, Ph.D., J.D.

Registration No.: 56,266

For

Megan E. Williams, Ph.D., J.D.

Registration No.: 43,270

LAHIVE & COCKFIELD, LLP

28 State Street

Boston, Massachusetts 02109

(617) 227-7400

(617) 742-4214 (Fax)

Attorney/Agent For Applicant